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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	1:17-md-02804-DAP MDL No. 2804 Judge Dan Aaron Polster
This Document Relates To:	
COUNTY OF SAN JOAQUIN, CITY OF STOCKTON, and MONTEZUMA FIRE PROTECTION DISTRICT, Plaintiffs, vs. PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS, INC., McKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCE BERGEN DRUG CORPORATION, and DOES 1-100, INCLUSIVE, Defendants.	Case No. 1:17-op-45017-DAP **AMENDED COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiffs County of San Joaquin, City of Stockton, and Montezuma Fire Protection District, on information and belief, allege:

I
INTRODUCTION

1. Plaintiffs spend millions of dollars each year to provide or pay for the health care, pharmaceutical care, and other necessary services and programs on behalf of indigents and otherwise eligible residents, including payments for prescription opium-like painkillers ("opioids"), which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants named below.

2. Plaintiffs also provide a wide range of other services on behalf of their residents, including, but not limited to, services for families and children, public assistance, medical transportation and emergency response, as well as law enforcement.

3. Plaintiffs are large employers in San Joaquin County. Plaintiffs fund their own health insurance plans for the benefit of their employees, through which they pay part or all of their employees' health care costs, including the cost of prescription drugs, such as opioids.

4. Opioids include brand-name drugs like OxyContin and Percocet and generics like oxycodone and hydrocodone. They are derived from, or possess properties similar to, opium and heroin, and, as such, they are highly addictive and dangerous and therefore are regulated by the United States Food and Drug Administration ("FDA") as so-called "controlled substances."

5. Defendants claim that opioids are useful for treating short-term post-surgical and trauma-related pain, and for palliative end-of-life care. Defendants, who knew that opioids were highly addictive, did not disclose that fact to either physicians or to the FDA; in fact, Defendants led both physicians and the FDA to believe just the opposite. Based on misinformation from Defendants, the FDA approved opioids for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for long-term pain relief. Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of pain by intentionally misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

6. Addiction is a spectrum of substance-use disorders that range from misuse and abuse of drugs to addiction.[1] Throughout this Complaint, "addiction" refers to the entire range of substance-abuse disorders. Individuals suffer negative consequences wherever they fall on the substance-use-disorder continuum.

7. Defendants knew that opioids are too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer ("chronic pain").

8. Defendants knew that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.[2]

9. Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (*i.e.*, not longer than 90 days) in managed settings (*e.g.*, hospitals) where the risk of addiction and other adverse outcomes was significantly minimized. To date, there is no uniform understanding of the long-term safety of opioids.

10. Despite the foregoing knowledge, in order to expand the market for opioids and realize increased profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common ailments as lower back pain, arthritis, and headaches.

11. Defendants accomplished that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the late 1990s, became more aggressive in or about 2006, and continues to the present.

12. Defendants accomplished their marketing campaign goal by convincing doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks, and that opioids could be safely used by most patients without threat of addiction, which Defendants knew was not true.

13. Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, and patients

[1] Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

[2] *See, e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

by engaging in a campaign to not only minimize the risks of long-term opioid use, but rather to promote such long-term opioid use, which has directly caused opioid addiction to increase exponentially with the direct and foreseeable result that there has been an increased demand for police, fire, medical, and other municipal services which directly caused Plaintiffs to incur increased expenses to care for their addicted citizens and employees, which they otherwise would not have incurred. The illegal acts of all Defendants have directly and foreseeably proximately caused injury and damage to the economies and prosperity of San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District.

14. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled.[3] In 2010, some 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. In that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).[4] While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.[5] By 2014, nearly two million Americans either abused or were dependent on opioids.[6]

15. Defendants' campaign has been extremely profitable for them. In 2012 alone, opioids generated $8 billion in revenue for drug companies.[7] Of that amount, $3.1 billion went to Purdue for its OxyContin sales.[8]

16. Defendants' marketing campaign has been extremely harmful to Americans. Overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half a million people died from such overdoses. Seventy-eight Americans die every day from an opioid overdose.[9]

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[3] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: http://www.cdc.gov/drugoverdose/epidemic/index.html (accessed March 31, 2016) (internal footnotes omitted).

[4] M. Daubresse, *et al*., Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013).

[5] L. Manchikanti, *et al*., Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective, 13 Pain Physician 401-435 (2010).

[6] CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids. Available at: http://www.cdc.gov/drugoverdose/opioids/prescribed.html (accessed March 31, 2016).

[7] B. Meier & B. Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).

[8] K. Eban, *Purdue Pharma's Painful Medicine*, Fortune Magazine (Nov. 9, 2011).

[9] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

17. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.[10] Between 30% and 40% of long-term users of opioids experience problems with opioid-use disorders.[11]

18. Opioid addiction and overdose have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."[12]

19. Defendants' marketing campaign has failed to achieve any material health care benefits. Since 1999, there has been no overall change in the amount of pain that Americans report.[13]

20. The National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies opioid Pharmaceutical Manufacturers' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*."[14] As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes " are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

21. The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion[15] and the commission of criminal acts to obtain opioids throughout the United States, including California and San Joaquin County. Consequently, public health and safety throughout the United States, including San

[10] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[11] J. Boscarino *et al.*, Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, 105(10) Addiction 1776 (2010); J. Boscarino *et al*., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) Journal of Addictive Diseases 185 (2011).

[12] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed March 31, 2016).

[13] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

[14] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed March 31, 2016) (emphasis added).

[15] According to the CDC, when prescription medicines are obtained or used illegally, it is called "drug diversion.

Joaquin County, has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, as well as by the failure to properly report increased distribution of opioids by Defendants, ultimately leading to widespread inappropriate use of the drug.

22. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiffs have been required to spend millions of dollars each year in their efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiffs have incurred and continue to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs, as well as direct injuries to each plaintiffs' economy which were proximately caused by Defendants' illegal acts and practices. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiffs and their residents.

II
JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction, if any, under 28 U.S.C. § 1332, insofar as the amount in controversy exceeds the sum or value of $75,000, and is between citizens of different States.

24. This Court has personal jurisdiction over Defendants because they conduct business in the State, purposefully direct or directed their actions toward the State, some or all consented to be sued in the State by registering an agent for service of process, they consensually submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State necessary to constitutionally permit the Court to exercise jurisdiction.

25. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District.

III
PARTIES

A. Plaintiffs

26. Plaintiffs, County of San Joaquin, City of Stockton, and Montezuma Fire Protection District are California municipal governmental entities who provide a wide range of services on behalf

of their residents, including services for families and children, public health, public assistance, law enforcement, and emergency care. Plaintiffs also fund their own health insurance plans for their employees

B. The Pharmaceutical Defendants

27. Defendant Purdue Pharma L.P, ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

28. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

29. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

30. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and more particularly in San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District, including the following:

Table 1. Purdue Opioids

Drug Name	Chemical Name	Schedule[16]
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone	Schedule II

31. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

[16] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

32. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Whales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

33. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

34. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids nationally and, more particularly, in San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District, including the following:

Table 2. Cephalon Opioids

Drug Name	**Chemical Name**	**Schedule**
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II

35. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and, more particularly, in San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District.

36. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

37. Defendant Janssen Pharmaceuticals, Inc., formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc. ("Janssen Pharmaceuticals"), wholly-owned subsidiary of J&J, is a Pennsylvania corporation with is principal place of business in Titusville, New Jersey.

38. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

39. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

40. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "J&J") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and,

more particularly, in San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District, including the following:

Table 3. J&J Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta[17]	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

41. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

42. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

43. Defendant Endo Pharmaceuticals, Inc. ("EPI"), a wholly-owned subsidiary of EHS, is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

44. EHS and EPI (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and, more particularly, in San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District, including the following:

Table 4. Endo Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II

45. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

[17] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

C. The Distributor Defendants

46. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business located at One Post Street, San Francisco, California. McKesson is a healthcare services and information technology company. McKesson partners with payers, hospitals, physician offices, pharmacies and pharmaceutical companies to provide prescription drugs and other medical devices and services to such customers. At all relevant times, McKesson distributed or directed the distribution of opioids to retail pharmacies nationwide, including to such purchasers in San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District. McKesson is the largest pharmaceutical distributor in North America, delivering one-third of all pharmaceuticals in North America.

47. On January 17, 2017, the U.S. Department of Justice ("DOJ"), on behalf of the Drug Enforcement Agency ("DEA"), announced that it had imposed a $150 million penalty on McKesson arising from the company's failure to report suspicious orders of opioids in violation of the Controlled Substances Act ("CSA") (the "2017 DEA Settlement"). As part of the 2017 DEA Settlement, McKesson must suspend sales of opioids from its distribution centers in Colorado, Ohio, Michigan, and Florida for several years. These suspensions were among the most severe ever imposed on a DEA-registered pharmaceutical distributor.

48. In connection with the 2017 DEA Settlement, the DEA revealed that since 2008 McKesson supplied various pharmacies with increasing amounts of opioids, and failed to report those suspicious orders in violation of federal law. In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA because of McKesson's failure to report suspicious orders of opioids to the DEA when discovered (the "2008 DEA Settlement"). Under the 2008 DEA Settlement, McKesson paid a $13.25 million penalty, and agreed to develop a Controlled Substance Monitoring Program ("CSMP") to ensure future compliance with the monitoring and reporting requirements of the CSA with respect to opioid shipments. But McKesson's CSMP was a failure which did not prevent ongoing misconduct and non-compliance with opioid monitoring and reporting, as confirmed by the 2017 DEA Settlement.

49. Defendant Cardinal Health, Inc. ("Cardinal") operates as a licensed distributor in California, licensed by the California State Board of Pharmacy and holding both wholesaler and out of state wholesaler distributor licenses. Cardinal's principal office is located in Dublin, Ohio. Cardinal operates a distribution center in Sacramento, California.

50. Defendant Amerisource Bergen Drug Corporation ("AmerisourceBergen") operates as a licensed distributor in California, licensed by the California State Board of Pharmacy and holding both wholesaler and out of state wholesaler distributor licenses. AmerisourceBergen is a Delaware corporation and its principal place of business is located in Chesterbrook, Pennsylvania.

51. The Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiffs allege the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Plaintiffs' community.

52. Plaintiffs are informed and believe and thereon allege that at all times mentioned herein, each of the above-named defendants was the agent of each of the remaining defendants, and that in doing the acts hereinafter set forth, each of the above-named defendants was acting within the course and scope of that agency, with the knowledge and consent and/or the ratification of each of the remaining defendants.

D. Doe Defendants

53. Defendants, DOES 1 through 100, inclusive, are sued herein by fictitious names. Their true names and capacities are unknown to Plaintiffs. When their true names and capacities are ascertained, Plaintiffs will amend this Complaint by inserting their true names and capacities herein. Plaintiffs are informed and believe and thereon allege that at all times mentioned herein, each of the fictitiously named defendants was responsible in some manner for the occurrences herein alleged, and that Plaintiffs' damages as herein alleged were proximately caused by those defendants. Each reference

in this Complaint to defendants or a specifically named defendant refers also to all defendants sued under fictitious names.

IV
FACTS RELEVANT TO ALL CAUSES OF ACTION

A. The Pain-Relieving and Addictive Properties of Opioids

54. The pain-relieving properties of opium have been recognized for millennia.

55. So has the magnitude of its potential for abuse and addiction. Opioids are related to illegal drugs like opium and heroin. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield – and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States,[18] and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

56. Due to concerns about their addictive properties, since 1970 opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA"). The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

57. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

58. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea,

[18] Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

59. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are "frighteningly high."[19] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

60. Opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, J&J's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

61. The Pharmaceutical Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[20] The FDA required that – going forward – opioid makers of long-acting formulations clearly communicate these risks in their labels.

[19] M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

[20] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed March 31, 2016).

62. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[21] .

63. The facts on which the FDA relied in 2013 and 2016 were well known to the Pharmaceutical Defendants in the 1990s when their deceptive marketing began, which facts these Defendants knowingly and intentionally suppressed.

B. Opioid Therapy Makes Patients Sicker Without Long Term Benefits

64. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. The Pharmaceutical Defendants are well aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, the Pharmaceutical Defendants failed to disclose the lack of evidence to support their use long-term and have failed to disclose the substantial scientific evidence that chronic opioid therapy actually makes patients sicker.

65. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long term use.

66. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.[22]

[21] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed March 31, 2016).

[22] A. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

67. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

68. While opioids may work in the short term, when they are used on a long-term basis, function generally declines, as does general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.[23]

69. The foregoing is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

70. For example, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment, and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

71. The Pharmaceutical Defendants knew about the medical problems associated with long-term use of opioids but chose not to change their marketing strategies and actively promoted the long-term use of opioids.

C. The Pharmaceutical Defendants' Scheme to Change Prescriber Habits and Public Perception

72. Before the Pharmaceutical Defendants began the marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used short-term, *e.g.*, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance.

[23] *See* A. Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

73. The market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. The Pharmaceutical Defendants recognized that if they could sell opioids not just for short-term pain relief but also for long-term chronic pain relief, they could achieve increased levels of sales and substantial profits. Further, these Defendants recognized that if they could cause their customers to become physically addicted to their drugs, they would increase the likelihood that their profits would continue indefinitely.

74. The Pharmaceutical Defendants knew that in order to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. The Pharmaceutical Defendants needed to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

75. The Pharmaceutical Defendants knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for patients, health care insurers, and health care payors, as well as increased costs to municipal governmental entities such as Plaintiffs who had an obligation to provide services to their citizens, including increased emergency response costs and law enforcement expenses.

76. Marshalling help from consultants and public relations firms, the Pharmaceutical Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, the Pharmaceutical Defendants instead sought to distort medical and public perception of existing scientific data.

77. Defendants, collectively and individually, poured vast sums of money into generating articles, continuing medical education courses ("CMEs"), and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new but phony "consensus" supporting the long-term use of opioids.

D. The Pharmaceutical Defendants Used "Unbranded" Marketing to Evade Regulations and Consumer Protection Laws

78. Drug companies' promotional activity can be "branded" or "unbranded," the latter of which refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can evade the extensive regulatory framework governing branded communications.

79. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks. The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to assess accurately the risks and benefits of drugs for their patients.

80. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") places further restrictions on branded marketing. It prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular." "Labeling" includes more than the drug's physical label; it also includes "all ... other written, printed, or graphic matter ... accompanying "the drug, including promotional material. The term "accompanying" s interpreted broadly to include promotional materials – posters, websites, brochures, books, and the like – disseminated by or on behalf of the manufacturer of the drug. Thus, Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

81. Branded promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated. If, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

82. The Pharmaceutical Defendants avoided using branded advertisements to spread their deceptive messages and claims regarding opioids. They did so in order to evade regulatory review.

83. Instead, the Pharmaceutical Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated unbranded marketing materials – materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, the Pharmaceutical Defendants presented information and instructions concerning opioids generally that were false and misleading.

84. By acting through third parties, the Pharmaceutical Defendants gave the false appearance that their messages reflected the views of independent third parties. Later, the Pharmaceutical Defendants would cite to these sources as "independent" corroboration of their own statements. Further, as one physician adviser to the Pharmaceutical Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not "push back" at having materials, for example, from the non-profit American Pain Foundation ("APF") on display in their offices, as they would with drug company pieces.

85. As part of their marketing scheme, the Pharmaceutical Defendants spread and validated their deceptive messages through the following unbranded vehicles ("the Vehicles"): (a) so-called "key opinion leaders" (*i.e.*, physicians who influence their peers' medical practice, including but not limited to prescribing behavior) ("KOLs"), who wrote favorable journal articles and delivered supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; and (e) unbranded patient education materials disseminated through groups purporting to be patient-advocacy and professional organizations ("Front Groups"), which exercised their influence both directly and indirectly through the Pharmaceutical Defendant-controlled KOLs who served in leadership roles in these organizations.

86. The Pharmaceutical Defendants disseminated many of their false, misleading, and unsupported messages through the Vehicles because they appeared to uninformed observers to be independent. Through unbranded materials, the Pharmaceutical Defendants presented information and instructions concerning opioids to the marketplace generally that were intentionally false and misleading, and upon which the marketplace had the right to rely and did rely on such false and misleading

information which proximately caused injury and damages to the entire marketplace and more particularly to San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District.

87. Even where such unbranded messages were disseminated through third-party Vehicles, the Pharmaceutical Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. As described herein, the Pharmaceutical Defendants' sales representatives distributed third-party marketing material to the Pharmaceutical Defendants' target audience that was intentionally deceptive.

88. The Pharmaceutical Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by third parties, ensuring that these Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, the Pharmaceutical Defendants exercised control over their deceptive messages and acted in concert with these third parties fraudulently to promote the use of opioids for the treatment of chronic pain.

89. The unbranded marketing materials that the Pharmaceutical Defendants assisted in creating and distributing either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks.

1. <u>The Pharmaceutical Defendants' Key Opinion Leaders</u>

90. The Pharmaceutical Defendants cultivated a select circle of doctors who were chosen and sponsored by these Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Pro-opioid doctors have been at the hub of the Pharmaceutical Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid doctors have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. The Pharmaceutical Defendants were able to exert control of each of these modalities through their KOLs.

91. In return for their pro-opioid advocacy, the Pharmaceutical Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish.

92. The Pharmaceutical Defendants cited and promoted their KOLs and studies or articles by their KOLs to broaden the chronic opioid therapy market. By contrast, Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy.

93. The Pharmaceutical Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of their agenda. These Defendants also kept close tabs on the content of the materials published by these KOLs.

94. In their promotion of the use of opioids to treat chronic pain, the Pharmaceutical Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Pharmaceutical Defendants.

2. <u>The Pharmaceutical Defendants' Corruption of Scientific Literature</u>

95. Rather than promote testing the safety and efficacy of opioids for long- term use, the Pharmaceutical Defendants led physicians, patients, and health care payors to believe that such tests had already been done when none had occurred. The Pharmaceutical Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material which the Pharmaceutical Defendants used to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

96. To accomplish their goal, the Pharmaceutical Defendants – sometimes through third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of favorable articles in academic journals.

97. The Pharmaceutical Defendants' plans for these materials did not originate in the departments within these Defendants' organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather,

they originated in the Pharmaceutical Defendants' marketing departments and with these Defendants' marketing and public relations consultants.

98. In these materials, the Pharmaceutical Defendants (or their surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, the Pharmaceutical Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that the Pharmaceutical Defendants' materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.

99. The Pharmaceutical Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when they knew that the articles distorted the significance or meaning of the underlying study.

100. The Pharmaceutical Defendants worked not only to create and promote favorable studies in the literature, but to discredit or suppress negative information. The Pharmaceutical Defendants' studies and articles often targeted articles that contradicted their claims or raised concerns about chronic opioid therapy. In order to do so, the Pharmaceutical Defendants – often with the help of third-party consultants – used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

101. The Pharmaceutical Defendants' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – was flatly inconsistent with their legal obligations. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

3. The Pharmaceutical Defendants' Misuse of Treatment Guidelines

102. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by the Pharmaceutical Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

a. Federation of State Medical Boards

103. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from The Pharmaceutical Defendants.

104. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies" and taught not that opioids could be appropriate in limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

105. A 2004 iteration of the 1998 Guidelines and the 2007 book, Responsible Opioid Prescribing, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including those in the San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District.

106. The publication of Responsible Opioid Prescribing was backed largely by drug manufacturers. In all, 163,131 copies of Responsible Opioid Prescribing were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medication (CME) activity for prescribers of opioid medications."

107. Defendants relied on 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

b. American Academy of Pain Medicine/American Pain Society Guidelines

108. American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from the Pharmaceutical

Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[24] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a paid consultant to Defendant Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

109. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received support from Defendants J&J, Cephalon, Endo, and Purdue.

110. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated in the San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District during the relevant time period, and were and are available online.

111. The Pharmaceutical Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

c. Guidelines that Did Not Receive Defendants' Support

112. The extent of the Pharmaceutical Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines – the authors of which did not accept drug-company funding – reached very different conclusions.

113. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well

[24] The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997). Available at http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf (as viewed 3/31/2016).

as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[25]

114. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[26]

115. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.[27]

4. <u>The Pharmaceutical Defendants' Misuse of Continuing Medical Education</u>

116. Continuing Medical Education ("CME") is a professional education program provided to doctors, who are required to attend a certain number and type of CME programs each year as a condition of maintaining their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in

[25] Laxmaiah Manchikanti, *et al*., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part TI, Evidence Assessment,* 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance,* 15 Pain Physician (Special Issue) S67-S116 (2012).

[26] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids* (2011).

[27] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf (accessed March 31, 2016).

medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

117. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, the Pharmaceutical Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Pharmaceutical Defendants' deceptions.

118. The Pharmaceutical Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and omit or downplay their risks and adverse effects.

119. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[28]

120. San Joaquin County physicians would have been invited to attend such meetings and some may have attended or reviewed the Pharmaceutical Defendants' sponsored CMEs during the relevant time period and were misled by them.

121. By sponsoring CME programs put on by Front Groups like APF, AAPM and others, the Pharmaceutical Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Pharmaceutical Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. The Pharmaceutical Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measure the effects of CMEs

[28] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).

on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

5. The Pharmaceutical Defendants' Misuse of Patient Education Materials and Front Groups

122. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[29] Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[30] Recognizing this phenomenon, the Pharmaceutical Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

123. The Pharmaceutical Defendants entered into arrangements with numerous Front Groups (*i.e.*, groups purporting to be patient-advocacy and professional organizations) to promote opioids. These organizations depend upon the Pharmaceutical Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting The Pharmaceutical Defendants' marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by the Pharmaceutical Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. The Pharmaceutical Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

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[29] Kanika Johar, An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices, 76 Albany L. Rev. 299, 308 (2013).

[30] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

a. American Pain Foundation

124. The most prominent of the Pharmaceutical Defendants' Front Groups was the American Pain Foundation ("APF"), which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

125. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to "educate" patients about their "right" to pain treatment with opioids. All of the programs and materials were intended to, and did, reach a national audience, including residents of the San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District.

126. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. APF board member, Dr. Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

127. APF held itself out as an independent patient advocacy organization, yet engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing. In reality, APF functioned largely as an advocate for the interests of the Pharmaceutical Defendants, not patients.

128. In practice, APF operated in close collaboration with Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by the Pharmaceutical Defendants. APF also assisted in marketing projects for these Defendants.

129. The close relationship between APF and the Pharmaceutical Defendants demonstrates APF's clear lack of independence, in its finances, management, and mission, and its willingness to allow these Defendants to control its activities and messages supports an inference that each Pharmaceutical Defendant that worked with it was able to exercise editorial control over its publications.

130. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately."[31]

[31] American Pain Foundation Website. Available at http://www.painfoundation.org (accessed March 31, 2016).

b. The American Academy of Pain Medicine

131. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of the Pharmaceutical Defendants, issued the treatment guidelines discussed herein, and sponsored and hosted CMEs essential to these Defendants' deceptive marketing scheme.

132. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

133. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs and Dr. Perry Fine, Dr. Portenoy, and Dr. Lynn Webster. Dr. Webster was elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are ... small and can be managed."

134. AAPM's staff understood that they and their industry funders were engaged in a common task. The Pharmaceutical Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

135. Like the tobacco industry, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, the Pharmaceutical Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superiority of opioids in the long-term treatment of chronic pain.

136. The Pharmaceutical Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated nationwide, including to San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District prescribers and patients.

137. One vehicle for The Pharmaceutical Defendants' marketing collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

138. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, J&J, and Purdue); doctors and nurses in the field of pain care; professional organizations (including AAPM, APS, and American Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")); and other like-minded organizations, almost all of which received substantial funding from the Pharmaceutical Defendants.

139. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[32] This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine the Pharmaceutical Defendants' marketing efforts. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." The Pharmaceutical Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

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[32] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

F. The Pharmaceutical Defendants' Misrepresentations

140. The Pharmaceutical Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy groups and medical societies, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and payors in San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District. These intentionally misleading promotional messages were intended by each of the Pharmaceutical Defendants to, and did, encourage patients to ask for, doctors to prescribe, and payors to pay for, chronic opioid therapy, which required Plaintiffs to expend additional funds and resources for an increased demand for police, fire, medical, and other municipal services to care for addicted citizens, including some of their own employees, and which proximately caused Plaintiffs' damages.

141. As doctors prescribe opioid drugs, the Pharmaceutical Defendants focused the bulk of their marketing efforts, and their multi-million-dollar budgets, on the professional medical community. Particularly because opioids are controlled substances, the Pharmaceutical Defendants knew doctors would not treat patients with common chronic-pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks of addiction. Accordingly, the Pharmaceutical Defendants did not disclose to prescribers, patients or the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Rather, each Pharmaceutical Defendant disseminated misleading and unsupported promotional materials that caused the target audience to believe their misleading materials were corroborated by scientific evidence. As a result, San Joaquin County doctors began prescribing opioids long-term to treat chronic pain – something that none would have considered prior to the Pharmaceutical Defendants' misleading campaign.

142. Drug company marketing materially impacts doctors' prescribing behavior. [33] Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their

[33] See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

products, and they are influenced by their patients' requests for particular drugs and payors' willingness to pay for those drugs.

143. As described in detail below, the Pharmaceutical Defendants individually and collectively:

- misrepresented the truth about how opioids lead to addiction;
- misrepresented that opioids improve function;
- misrepresented that addiction risk can be managed;
- misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- falsely claimed that withdrawal is simply managed;
- misrepresented that increased doses pose no significant additional risks;
- falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

144. The Pharmaceutical Defendants' misrepresentations were aimed at doctors, patients, and payors, including San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District, all three of whom paid for their employees' opioid addictions. Underlying each of the Pharmaceutical Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was their collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.[34]

1. The Pharmaceutical Defendants, Acting Individually And Collectively, Misrepresented The Truth About How Opioids Lead To Addiction

145. The Pharmaceutical Defendants' false representation that opioids are rarely addictive is central to these Defendants' scheme. Through their well-funded, comprehensive, aggressive marketing efforts, the Pharmaceutical Defendants succeeded in changing the perceptions of many physicians, patients, and health care payors and in getting them to accept that addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for pain. That, in turn, directly led to the expected, intended, and foreseeable result that doctors prescribed more opioids to more patients – thereby enriching

[34] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

the Pharmaceutical Defendants – and which proximately caused all three Plaintiffs to expend funds and resources caring for their citizens and employees and which also proximately caused injuries to the economies of San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District.

146. Each of the Pharmaceutical Defendants claimed that the potential for addiction from its drugs was relatively small or non-existent, even though there was no scientific evidence to support those claims.

147. For example, Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

148. For another example, Endo sponsored a website, painknowledge.com, through APF, which claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that as long as a prescription is given, opioid use will not become problematic.

149. For another example, J&J sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF, which, as set forth in the excerpt below, described as a "myth" the fact that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

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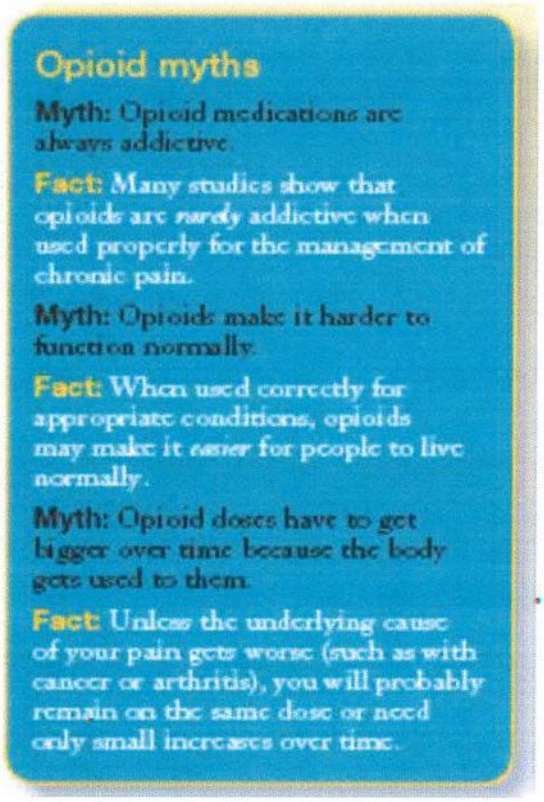


150. The overall presentation here suggests that the addiction rate is so low as to be immaterial. The language also implies that as long as a prescription is given, opioid use is unlikely to lead to addition, which is untrue and which the Pharmaceutical Defendants knew was untrue.

151. The guide states as a "fact" that "Many studies" show that opioids are rarely addictive when used for chronic pain. In fact, no such studies exist.

152. For another example, Purdue sponsored and J&J provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Again, the overall presentation suggests that the addiction rate is so low as to be immaterial.

153. For another example, Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which inaccurately claimed that less than 1% of children prescribed opioids would become addicted.[35] This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

[35] In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.

154. For another example, in the 1990s, Purdue amplified the pro-opioid message with promotional videos and featuring Dr. Portnoy and other doctors in which it was claimed, "the likelihood that treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[36]

155. Rather than honestly disclose the risk of addiction, the Pharmaceutical Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, these Defendants turned the tables: they suggested that doctors who failed to treat their patients' chronic pains with opioids were failing their patients and risking professional discipline, while doctors who relieved their pain using long-term opioid therapy were following the compassionate (and professionally less risky) approach. The Pharmaceutical Defendants claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. The Treatment Options guide funded by Purdue and Cephalon states "[d]espite the great benefits of opioids, they are often underused." The APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, laments that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include ... misconceptions about opioid addiction."[37]

156. *Let's Talk Pain*, sponsored by APF, AAPM and J&J, likewise warns, "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say, "[b]ecause of the potential for abusive and/or addictive behavior, many health care professionals have been reluctant to prescribe opioids for their patients.... This prescribing environment is one of many barriers that may contribute to the under-treatment of pain, a serious problem in the United States."

157. The Pharmaceutical Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in

[36] Excerpts from one such video, including the statement quoted here, may be viewed at http://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[37] This claim also appeared in a 2009 publication by APF, *A Reporter's Guide*.

quality of life could be alleviated by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

158. Although opioids may initially improve patients' function by providing pain relief in the short-term, there exist no controlled studies of the use of opioids beyond 12 weeks and no evidence that opioids improve patients' function in the long-term. Indeed, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[38] Despite this lack of evidence of improved function, and the existence of evidence to the contrary, the Pharmaceutical Defendants consistently promoted opioids as capable of improving patients' function and quality of life without disclosing the lack of evidence for this claim.

159. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."[39]

160. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007), sponsored by drug companies including Cephalon, Endo and Purdue, taught that relief of pain itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

161. Cephalon and Purdue sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids "give [pain patients] a quality of life we deserve." The Treatment Options guide notes that non-steroidal anti-inflammatory drugs (*e.g.*, Aspirin or Ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids. The APF distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report, and it is currently available online.

162. Endo sponsored a website, painknowledge.com, through the APF, which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was

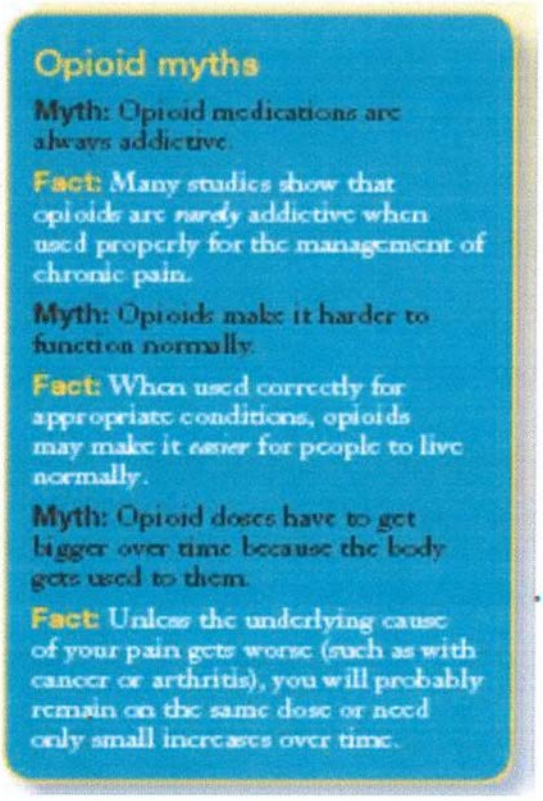
[38] Jeffrey Dersh, *et al.*, Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders, 33(20) Spine 2219-27 (Sept. 15, 2008).

[39] Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, *King Pharmaceuticals*, Re: NDA 21-260 (March 24, 2008).

worse." Elsewhere, the website touted improved quality of life as well as "improved function" as benefits of opioid therapy.

163. J&J sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

164. As set forth in the excerpt below, the guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. The targeting of older adults also ignored heightened opioid addiction risks in this population.



Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

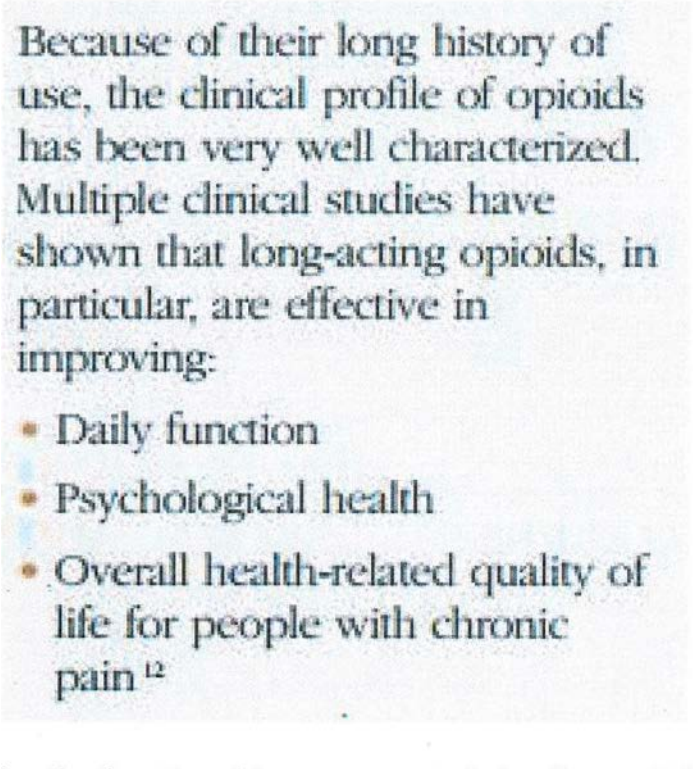
Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

165. J&J sponsored a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and American Society for Pain Management Nursing whose participation in *Let's Talk Pain* J&J financed and orchestrated. This website featured a video interview, which was edited by J&J personnel,

claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

166. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management (2011)*, which accurately claimed that "multiple clinical studies" have shown opioids are effective in improving daily function, psychological health, and Endo distributed a patient education pamphlet edited by KOL Defendant Dr. Portenoy entitled Understanding Your Pain: Taking Oral Opioid Analgesics. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that patients prescribed opioids for genuine pain will not become addicted, which is unsupported and health related quality of life for chronic pain patients," with the implication these studies presented claims of long-term improvement.


Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain [12]

167. The sole reference for the functional improvement claim: (a) noted the absence of long-term studies, and (b) actually stated, "For functional outcomes, the other analgesics were significantly more effective than were opioids."

168. Purdue sponsored and J&J provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning" (emphasis in the original).

2. The Pharmaceutical Defendants, Acting Individually And Collectively, Misrepresented That Addiction Risk Can Be Effectively Managed

169. The Pharmaceutical Defendants each continue to maintain to this day that most patients safely can take opioids long-term for chronic pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, these Defendants have come to admit that some patients could become addicted, but that doctors can effectively avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

170. There are three fundamental flaws in the Pharmaceutical Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Even if the tools are effective, they may not always be applied correctly, and are subject to manipulation by patients. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through screening can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

171. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. An Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[40] Furthermore, attempts to treat high-risk patients, like those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug

[40] The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain, Agency for Healthcare Res. & Quality (Sept. 19, 2014).

screening are not proven to work in the real world, even when well meaning, but doctors were misled to employ them.[41]

172. The Pharmaceutical Defendants' misrepresentations regarding the risk of addiction from chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors (collectively "GPs"), who treat many chronic conditions but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. One study conducted by pharmacy benefits manager Express Scripts concluded, after analyzing 2011-2012 narcotic prescription data of the type regularly used by the Pharmaceutical Defendants to market their drugs, that, of the more than half million prescribers of opioids during that time period, only 385 were identified as pain specialists.[42]

173. In materials they produced, sponsored, or controlled, the Pharmaceutical Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain. The Pharmaceutical Defendants' marketing scheme contemplated a "heads we win; tails we win" outcome: patients deemed low risk were to receive opioids on a long-term basis without enhanced monitoring, while and patients deemed high risk were also to receive opioids on a long-term basis but with more frequent visits, tests and monitoring – with those added visits, tests, and monitoring to be paid for or reimbursed by payors, including Plaintiffs. This, of course, led to a "heads you lose; tails you lose" outcome for patients – all of whom are subjected to an unacceptable risk of addition – and for payors, including Plaintiffs.

174. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

175. Endo paid for a 2007 supplement available for continuing education credit in the Journal of Family Practice written by a doctor who became a member of Endo's speaker's bureau in 2010. This

[41] M. Von Korff, *et al*., *Long-term opioid therapy reconsidered*, 15595, Annals Internal Med. 325 (Sept. 2011); L. Manchikanti, *et al*., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 Pain Physician S1 (2012).

[42] Express Scripts Lab, A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain (December 2014).

publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by Dr. Webster and linked to J&J or (ii) the *Screener and Opioid Assessment for Patients with Pain*, and (iii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

176. Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

3. The Pharmaceutical Defendants, Acting Individually And Collectively, Misled Physicians, Patients, And Payors Through The Use Of Misleading Pseudowords Like "Pseudoaddiction"

177. The Pharmaceutical Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe ever more opioids despite signs that the patient was addicted. The word "pseudoaddiction" was concocted by Dr. J. David Haddox, who later went to work for Purdue, and was popularized in opioid therapy for chronic pain by Dr. Portenoy, who consulted for Pharmaceutical Defendants Cephalon, Endo, J&J, and Purdue. Much of the same language appears in other Pharmaceutical Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction" – as if patients could not experience both.

178. In the materials they produced, sponsored, or controlled, the Pharmaceutical Defendants misrepresented that the concept of "pseudoaddiction" is substantiated by scientific evidence.

179. Cephalon and Purdue sponsored the Federation of State Medical Boards' Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are in fact signs of genuine addiction, are all really signs of "pseudoaddiction."

180. Purdue did not mention that the author who concocted both the word and the phenomenon it purported to describe became a Purdue Vice President; nor did Purdue disclose the lack of scientific evidence to support the existence of "pseudoaddiction."[43]

[43] J. David Haddox & David E. Weissman, *Opioid pseudoaddiction – an iatrogenic syndrome*, 36(3) Pain 363 (Mar. 1989).

181. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, PartnersAgainstPain.com, in 2005, and upon information and belief circulated this pamphlet after 2007. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but rather was indicative of "pseudoaddiction" caused by untreated pain. It also stated, "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated .... Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

4. The Pharmaceutical Defendants, Acting Individually And Collectively, Claimed Withdrawal Is Simply Managed

182. In an effort to underplay the risk and impact of addiction, the Pharmaceutical Defendants claimed that, while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed, if and when pain relief is no longer desired, by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. The Pharmaceutical Defendants fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids – an adverse effect that also makes it less likely that patients will be able to stop using the drugs.

183. In materials the Pharmaceutical Defendants produced, sponsored, and/or controlled, they made misrepresentations to persuade doctors and patients that withdrawal from their opioids was not a problem and they should not be hesitant about prescribing or using opioids. These claims were not supported by scientific evidence.

184. A CME sponsored by Endo entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering a patient's opioid dose by 10% to 20% per day for ten days. This claim was misleading because withdrawal in a patient already physically dependent would take longer than ten days – when it is successful at all. [44]

[44] See Jane Ballantyne, New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain With Opioids, 21(5) Pain Clinical Updates (Dec. 2013).

185. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

5. The Pharmaceutical Defendants, Acting Individually And Collectively, Misrepresented That Increased Doses Pose No Significant Additional Risks

186. The Pharmaceutical Defendants claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of the Pharmaceutical Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.

187. In materials the Pharmaceutical Defendants produced, sponsored or controlled, they instructed patients and prescribers that patients could remain on the same dose indefinitely, assuaging doctors' concerns about starting patients on opioids or increasing their doses during treatment, or about discontinuing their patients' treatment as doses escalated. These claims were not supported by scientific evidence.

188. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide taught that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the true figure was closer to 3,200 at the time.[45]

189. Cephalon sponsored a CME written by KOL Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

[45] Robert E. Tarone, *et al*., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

190. Endo sponsored a website, *painknowledge.com*, through APF, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

191. Endo distributed a patient education pamphlet edited by KOL Defendant Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was published on Endo's website. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. ... You won't 'run out' of pain relief."

192. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high-dose opioids. This publication is still available online.

193. Purdue sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME was edited by KOL Dr. Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

6. The Pharmaceutical Defendants, Acting Individually And Collectively, Deceptively Omitted Or Minimized The Adverse Effects Of Opioids And Overstated The Risks Of Alternative Forms Of Pain Treatment

194. In materials they produced, sponsored or controlled, the Pharmaceutical Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. None of these claims was supported by scientific evidence.

195. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, the Pharmaceutical Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[46] hormonal dysfunction;[47] decline in

[46] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).
[47] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001).

immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[48] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety. Post-traumatic stress disorder and anxiety also often accompany chronic pain symptoms.[49]

196. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the figure is closer to 3,200.[50] *Treatment Options* also warned that risks of NSAIDS increase if "taken for more than a period of months," with no corresponding warning about opioids.

197. Endo sponsored a website, painknowledge.com, through APF, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects that omitted significant adverse effects including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

198. J&J and Purdue sponsored and Endo provided grants to APF to distribute *Exit Wounds* (2009), which omits warnings of the risk of potentially fatal interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder.

199. As a result of the Pharmaceutical Defendants' campaign of deception, promoting opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[51]

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[48] See Bernhard M. Kuschel, The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study, Eur. J. Pub. H. (July 31, 2014).

[49] Karen H. Seal, Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan, 307(9) J. Am. Med. Ass'n 94047 (2012).

[50] Robert E. Tarone, *et al.*, Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

[51] M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(*10)* Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29%

G. The Pharmaceutical Defendants' Promotion of Their Branded Drugs Also Was Deceptive

200. While the Pharmaceutical Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Pharmaceutical Defendant promoted opioids for chronic pain through sales representatives (which these Defendants called "detailers" to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide, including in San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District. By establishing close relationships with doctors, the Pharmaceutical Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

201. The Pharmaceutical Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors' prescribing habits. In accordance with common industry practice, these Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States, including doctors in San Joaquin County.

H. The Pharmaceutical Defendants Knew That Their Marketing of Chronic Opioid Therapy Was False, Unfounded, and Dangerous and Would Harm Plaintiffs and their Residents

202. The Pharmaceutical Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct. The Pharmaceutical Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization,

between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. *See also* J. Mafi, *et al.*, *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

203. The Pharmaceutical Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and payors to pay for their opioids for chronic pain.

204. When they began their deceptive marketing practices, the Pharmaceutical Defendants recklessly disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as reasonably foreseeable harm began to occur, these Defendants were well aware that it was occurring. The Pharmaceutical Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon – overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

I. The Pharmaceutical Defendants Entered into and Engaged in a Civil Conspiracy

205. The Pharmaceutical Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein, and intended to benefit both independently and jointly from their conspiratorial enterprise.

206. The Pharmaceutical Defendants reached an agreement between themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

207. This network is interconnected and interrelated which is relied upon the Pharmaceutical Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by the Pharmaceutical Defendants, and these Defendants relied upon the materials to intentionally mislead consumers and medical providers of the appropriate uses, risks and safety of opioids.

208. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Pharmaceutical Defendants committed overt acts in furtherance of their conspiracy.

J. The Pharmaceutical Defendants Actively Concealed their Misrepresentations

209. The Pharmaceutical Defendants took steps to avoid detection of, and to actively conceal, their deceptive marketing and conspiratorial behavior.

210. The Pharmaceutical Defendants disguised their own roles in the deceptive marketing by funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. The Pharmaceutical Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of the Pharmaceutical Defendants' false and misleading statements about opioid use for chronic pain. The Pharmaceutical Defendants never disclosed that they were behind Front Groups or KOLs because they did not want medical professionals, patients, payors, or the public-at-large to know of their involvement with such groups.

211. While the Pharmaceutical Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. These Defendants exerted their considerable influence on the purportedly "educational" or "scientific" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not public.

212. In addition to hiding their own role in generating the deceptive content, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear these items were accurate, truthful, and supported by substantial scientific evidence. The Pharmaceutical Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions the materials did no support. The true lack of support for the Pharmaceutical Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions. The false and misleading nature of the Pharmaceutical Defendants' marketing was not known to, nor could it reasonably have been discovered by, Plaintiffs or their citizens.

213. The Pharmaceutical Defendants also concealed their participation by extensively using the public relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.

214. The Pharmaceutical Defendants concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the existence of claims that Plaintiffs now assert. Plaintiffs did not discover the existence and scope of the Pharmaceutical Defendants' industry-wide false statements and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through the public statements, marketing, and advertising, the Pharmaceutical Defendants' deceptions deprived Plaintiffs of actual or implied knowledge of facts sufficient to put them on notice of potential claims.

K. The Distributor Defendants Unlawfully Distributed Opioids

215. The Distributor Defendants owe a duty under both federal law (21 U.S.C. § 823, 21 CFR 1301.74) and California law (*see, e.g.*, Cal. Bus. & Prof. Code § 4169.1) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiffs' community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiffs' community.

216. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

217. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate cause of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiffs' community.

218. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and in Plaintiffs' community. This diversion and the epidemic are direct causes of harms for which Plaintiffs seek to recover here.

219. The opioid epidemic in the State, including *inter alia* in Plaintiffs' community, remains an immediate hazard to public health and safety.

220. The opioid epidemic in Plaintiffs' Community is a temporary and continuous public nuisance and remains unabated.

221. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

222. McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)." McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers." Due to these violations, McKesson agreed that its authority to distribute controlled substances from numerous facilities would be partially suspended.

223. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA. In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so. The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with

McKesson's obligations." As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.

224. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

225. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

226. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to

immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.

227. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

228. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity." Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

229. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country." Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

230. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert. The Plaintiffs did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

231. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the State and Plaintiffs' community.

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L. The Relationship Between Pharmaceutical Defendants and Distributor Defendants is Symbiotic, and Created the Opioid Epidemic

232. Although the Distributor Defendants had the ability and duty to prevent opioid diversion, they continued to allow it, which enabled the opioid crisis to reach epidemic proportions.

233. The Distributor Defendants have supplied huge quantities of prescription opioids in the State with actual or constructive knowledge that the opioids were ultimately being consumed for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so. All the while, the Pharmaceutical Defendants profited from the increasing volume of sales to the Distributor Defendants on the basis of these sales for non-medical purposes.

234. The Distributor Defendants knew or should have known that the amounts of opioids that they allowed to flow into the State were far in excess of what could be consumed for medically-necessary purposes in Plaintiffs' community. In turn, the Pharmaceutical Defendants turned a blind eye to the fact that the volume of opioids being supplied to the Distributor Defendants simply could not be supported by any medically-necessary purpose.

235. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have protected against the danger of opioid diversion by: taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; more carefully scrutinizing the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic factors concerning the increasing demand for narcotic painkillers in certain communities; proactively providing information to pharmacies and retailers about opioid diversion; and at a bare minimum, following applicable statutes, regulations, professional standards, and guidance from government agencies.

236. The Distributor Defendants made insufficient efforts to monitor or to perform due diligence to ensure that the controlled substances they had furnished were not being diverted to illegal uses.

237. On information and belief, the Distributor Defendants compensated certain of their employees, at least in part, based on the volume of their sales of opioids, thus improperly creating incentives that contributed to opioid diversion and the resulting epidemic of opioid abuse. In this regard, the profit motives of the Pharmaceutical Defendants and the Distributor Defendants were perfectly aligned so that all Defendants realized financial gain on account of the opioid epidemic.

238. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market with highly-addictive opioids would allow opioids to fall into the hands of addicts, criminals, vulnerable populations, and other unintended users. It was also reasonably foreseeable to the Distributor Defendants that, when unintended users gained access to opioids, tragic preventable injuries would result, including addiction, overdose, and death in Plaintiffs' community. Yet none of this could have happened without the Pharmaceutical Defendants supplying the opioids in the first place, creating a close and continuous relationship among all Defendants.

239. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic and would create access to opioids by unauthorized users, which, in tum, would perpetuate the cycle of addiction, demand, and illegal transactions. This situation only redounded to the benefit of the Pharmaceutical Defendants.

240. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed in and to the State were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to Plaintiffs' community.

241. The Distributor Defendants were aware of widespread prescription opioid abuse throughout the country and in the State, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas and in such quantities, and with such frequency that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

242. The use of opioids by citizens who were addicted or who did not have a medically-necessary purpose to use opioids could not occur without the knowing cooperation and assistance of the Distributor Defendants, working in concert with the Pharmaceutical Defendants. If all Defendants had

implemented and enforced effective controls to guard against diversion, Plaintiffs' community would have avoided significant injury.

243. All Defendants made substantial profits from the distribution of opioids in Plaintiffs' community, including opioids that they knew or should have known were being diverted to improper channels.

V
CAUSES OF ACTION

FIRST CAUSE OF ACTION
PUBLIC NUISANCE
(Against All Defendants)

244. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

245. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of citizens in San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District by their production, promotion, and marketing of opioids for use by residents of San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District.

246. Defendants' conduct is unreasonable.

247. Defendants' conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage to the property of San Joaquin County, the City of Stockton, and the Montezuma Fire Protection District.

248. Defendants' conduct constitutes a public nuisance.

249. Defendants' conduct directly and proximately caused injury and damages to Plaintiffs because they had to expend excess funds on police, fire, medical, and other municipal services than they otherwise would have spent, including damages to each Plaintiff's economy.

250. Plaintiffs and their residents suffered special injuries distinguishable from those suffered by the general public.

SECOND CAUSE OF ACTION
FALSE REPRESENTATIONS
(Against All Pharmaceutical Defendants)

251. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

252. The Pharmaceutical Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiffs and their residents to induce them to purchase, administer, consume, and pay for opioids as set forth in detail above.

253. The Pharmaceutical Defendants knew or should have known that Plaintiffs would be adversely impacted economically by their misrepresentations in that certain of Plaintiffs' citizens would become addicted to the Pharmaceutical Defendants' opioids which, in turn, would cause Plaintiffs to expend excess funds on police, fire, medical, and other municipal services to care for their citizens and employees, thereby proximately causing Plaintiffs' injuries and damages. Therefore, the Pharmaceutical Defendants owed a duty of care to each of the Plaintiffs.

254. The Pharmaceutical Defendants knew at the time that they made their misrepresentations and omissions that they were false.

255. The Pharmaceutical Defendants intended that Plaintiffs and their residents would rely on their misrepresentations and omissions.

256. Plaintiffs and their residents reasonably relied upon the Pharmaceutical Defendants' misrepresentations and omissions.

257. By reason of their reliance on the Pharmaceutical Defendants' misrepresentations and omissions of material fact Plaintiffs suffered actual pecuniary damages proximately caused by the Pharmaceutical Defendants' false representations, which required Plaintiffs to expend additional funds on police, fire, medical, and other municipal services than they otherwise would not have incurred.

258. The Pharmaceutical Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

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THIRD CAUSE OF ACTION
UNJUST ENRICHMENT
(Against All Defendants)

259. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

260. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by Plaintiffs and their citizens.

261. In exchange for the opioid purchases, and at the time Plaintiffs and their residents made these payments, Plaintiffs and their residents expected that Defendants had provided all of the necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks, and had properly reported the sale of opioids in San Joaquin County as is required of distributors of scheduled drugs.

262. The Pharmaceutical Defendants knew or should have known that Plaintiffs would be adversely impacted economically by their misrepresentations in that certain of Plaintiffs' citizens would become addicted to the Pharmaceutical Defendants' opioids which, in turn, would cause Plaintiffs to expend excess funds on police, fire, medical, and other municipal services to care for their citizens and employees, thereby proximately causing Plaintiffs' injuries and damages. Therefore, the Pharmaceutical Defendants owed a duty of care to each of the Plaintiffs.

263. Defendants have been unjustly enriched at the expense of Plaintiffs.

FOURTH CAUSE OF ACTION
COMMON LAW *PARENS PATRIAE*
(Against All Defendants)

264. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

265. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by Plaintiffs and their residents.

266. In exchange for the opioid purchases, and at the time Plaintiffs and their residents made these payments, Plaintiffs and their residents expected that Defendants had provided all of the necessary

and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

267. As a result of Defendants' wrongdoing as alleged in this complaint, each Plaintiff's economy and prosperity has been injured for which each claims injunctive and monetary relief *parens patriae*.

VI
PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand judgment against Defendants, jointly and severally, awarding Plaintiffs:

1. Compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages;

2. Punitive damages;

3. Interest, costs, and disbursements; and

4. Such other and further relief as this Court deems just and proper.

VII
DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury in this action on all claims so triable.

Dated: May 24, 2018

PARISH GUY CASTILLO, PC

By /s/ William H. Parish
WILLIAM H. PARISH
Attorneys for Plaintiffs

Dated: May 24, 2018

LAW OFFICES OF FRANCIS O. SCARPULLA

By /s/ Francis O. Scarpulla
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Counsel for City of Stockton

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of May 2018, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF System.

/s/ Francis O. Scarpulla
FRANCIS O. SCARPULLA